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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,260

07/07/2006

Tae Ki Yoon

3416-101

1802

6449

7590

06/30/2010

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

1425 K STREET, N.W.

SUITE 800

WASHINGTON, DC 20005

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

NOTIFICATION DATE

DELIVERY MODE

06/30/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,260	<b>Applicant(s)</b> YOON ET AL.	
	<b>Examiner</b> Valarie Bertoglio	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04/05/2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's reply filed on 04/05/2010 is acknowledged.

Claims 2,4,7 and 8 are cancelled. Claims 1,3,5 and 6 are pending and under consideration.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3 and 5-6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon, 2000; IDS) in view of US 5,976,567 (published 11/02/1999) and further in view of (Martino et al, 1996; IDS). The rejection, set forth below, is maintained.

Yoon taught exposing mature human oocytes to cryoprotectant prior to loading onto an electron microscope grid. The grid was plunged into liquid nitrogen and stored in liquid nitrogen until devitrification (paragraphs 3 and 4). Yoon taught devitrifying the oocytes prior to ICSI.

Yoon did not teach use of a gold grid or use of nitrogen slush.

However, at the time of filing it was well known to one skilled in the art that electron microscopy grids were made of a number of different materials including copper and gold. Both copper and gold are excellent conductors useful in quick freezing of tissues. For example, '567 taught placing vesicles on a gold electron microscopy grid and vitrifying the vesicles by rapid freezing in liquid ethane cooled with liquid nitrogen (col. 40, lines 2-7). Thus, it would have merely been a matter of design choice to the skilled artisan to choose a gold grid from amongst the many well-known choices of grids for use in vitrification.

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Additionally, the use of nitrogen slush for rapid cooling of oocytes on electron microscope grids was taught by Martino et al. Martino taught the use of both liquid nitrogen and nitrogen slush for cryopreservation of oocytes. Martino taught that rapid cooling can have damaging effects on oocytes and the damage that occurs is species specific. One means of experimenting to obtain higher effective freezing rates is to alter the freezing rate by use of straws vs. grids as well as use of nitrogen slush as opposed to liquid nitrogen. Martino suggests that some species might freeze better in slush while others would fare better in liquid nitrogen (see, in particular, page 1066, col.2).

In *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the Supreme Court particularly emphasized “the need for caution in granting a patent based on a combination of elements found in the prior art,” (*Id.* At 1395) and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” (*Id.* At 1395.) In the instant case, with regard to the use of gold grids, the difference between that claimed and that taught in the art amounts to no more than a simple substitution of one known equivalent for another to obtain predictable results.

Additionally, it would have been obvious to substitute nitrogen slush for the freezing of oocytes in place of the liquid nitrogen used by Yoon. Martino taught that different sized oocytes would be affected differently from different rates of cooling. Thus, one would have been motivated to alter the freezing rate of human oocytes by use of slush nitrogen in place of liquid nitrogen.

Applicant argues that Wheeler (US 5,976,567) teaches the use of electron microscopy grids for purposes other than vitrification of oocytes and Wheeler fails to teach vitrification of oocytes. Therefore, Applicants argue, one would not have been motivated to use a gold grid from Wheeler in vitrifying oocytes as taught by Yoon as the technologies of the two references are different.

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In response, Applicant's argument is appreciated. However, because Yoon taught the use of an electron microscopy grid for vitrification of oocytes, one of skill in the art would look to the electron microscopy art for different types of electron microscopy grids. This is especially true in light of the teachings of Martino discussing the differences between various species of oocytes and the different requirements for freezing rates. One of skill in the art would attempt to find the best freezing rate for a particular species by varying the temperature of the coolant (i.e. liquid vs. slush) as well as the material the grid is made of (i.e. copper vs gold).

Applicant argues that the Examiner took the position that some species of oocytes might freeze better in slush nitrogen in comparison to liquid nitrogen and that this stance is not supported by Martino. Applicant states that Martino teaches both bovine and Drosophila oocytes have high chilling sensitivity compared to mouse oocytes and that ultra rapid cooling is used to vitrify bovine and Drosophila oocytes while conventional cooling is found to be successful with mouse oocytes. The issue, however, is that Martino uses liquid nitrogen for both rapid and conventional cooling. Therefore, Martino is not suggesting use of slush nitrogen. In response, Martino shows differential success with liquid and slush nitrogen. The art, when taken as a whole, shows that different species are most successfully vitrified using different cooling rates. Cooling rates can be affected by use of different combinations of liquid/slush nitrogen and different freezing platforms, copper grids/gold grids/straws etc.) It is a matter of routine experimentation and design choice to determine the best combination for various oocytes. While the art fails to teach the best combination for use in vitrifying human oocytes as claimed, the claimed combination is merely a combination of familiar elements according to known methods.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing

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date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio/  
Primary Examiner, Art Unit 1632